JUN - 8. 2012

510(K) SUMMARY

510(K) Number K 120465

5.1 Applicant's Name: EarlySense Ltd.
12 Tzvi Street,
Ramat Gan, Israel

5.2 Contact Person: Dalia Argaman
EarlySense Ltd.
12 Tzvi Street,
Ramat Gan, Israel
Tel: +972 (3) 752 – 2330
Fax: +972 (3) 752 – 2340
Email: Dalia.Argaman@Earlysense.com

5.3 Date Prepared: April 2012

5.4 Trade Name: EarlySense (EverOn™) System

5.5 Classification Name: Breathing frequency monitor (868.2375)
monitor, cardiac (incl. cardiotachometer & rate alarm) (870.2300)
Oximeter (870.2700)

5.6 Product Code: BZQ, DRT, and DQA

5.7 Device Class: Class II

5.8 Predicate Devices:

- EverOn 1.0 (EarlySense Ltd.), cleared under K092062.
- Avant™ 9600 Pulse Oximeter (Nonin Medical Inc.), cleared under K040589
- LifeShirt System with VivoLogic Analysis Software (VivoMeterics Inc.), cleared under K011903

5.9 Intended Use / Indication for Use:

The EarlySense (EverOn) System is intended for continuous measurement of respiration rate, heart rate and movement, in an automatic contact-less manner, at home, hospital or clinic setting. The system is indicated for use in children, adolescents and adults. The operation of the EarlySense has been studied in children (weight ≥ 10 Kg) and adults (weight <111 Kg) during

sleep and resting condition. In addition, EarlySense (EverOn) System can continuously monitor oxygen saturation of arterial hemoglobin (SPO2) using pulse oximetry in pediatric (ages 2 years and older), adolescents, and adults at home, hospital, or clinical settings.

5.10 Device Description

The EarlySense (EverOn) System consists of the following main components:

- A piezoelectric Sensing Unit placed under the mattress or mattress pad.
- Bedside Unit with Proprietary recording and data analysis software
- OEM Oximetry Module (optional)

The EarlySense (EverOn) System is designed for continuous and contact-less monitoring of respiration rate, heart rate and movement. The under mattress Sensing Unit includes a piezoelectric sensor, which converts mechanical movements into an electric signal. The principles and the mode of operation for the capability of contactless monitoring of the EarlySense (EverOn) is identical to the cleared EverOn 1.0 (K092062). The EarlySense interfaces with a pulse oximeter OEM module (optional feature) and can therefore also monitor oxygen saturation. The oximetry module is connected externally via UART (RS232/TTL) to the Bedside unit. A compatible oximetry sensor is then attached to the patient's finger and the monitor begins to continuously display oximetry data (e.g. SpO_2).

The Bedside Unit, processes inputted signals, displays the patient's parameters, and generates alerts (respiration rate, heart rate, movement, and SpO_2) as per set thresholds when needed. The continuously accumulated data from the monitored period are displayed on the bedside unit and may optionally be communicated, via wired or via wireless LAN communication to a dedicated secondary display (EarlySense Central Display Station (CDS) - cleared under K100376 and K110521). Analysis of the results may be performed either on-line during the monitoring session, or later, off-line. Data for each patient is recorded and can therefore also be retrieved and presented.

5.11 Performance Standards

The EarlySense System complies with voluntary standards such as:

- Medical electrical equipment- general requirements for safety. Part 1: General Requirements for Safety. IEC 60601-1(1988): +A1(1991) +A2(1995);
- Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests. EN/IEC 60601-1-2 (2007)
- Medical device software - Software life cycle processes. IEC 62304 (2006)
- Medical devices – Application of risk management to medical devices. ISO 14971 (2009)

5.12 Substantial Equivalence

Intended use and Technological Characteristics

The EarlySense (EverOn), subject to this submission, is similar to the EverOn 1.0 predicate device with the following changes: (1) optional interface with a pulse oximeter OEM module and therefore monitoring of oxygen saturation and (2) operation on a Linux platform. By incorporating an oximeter module into the EarlySense System, two cleared scientific technologies are combined into one System. The intended use and indications for use of the EarlySense is similar and encompassed within the intended use and indications for use of its predicate devices. Specifically, with the exclusion of monitoring oxygen saturation, the proposed intended use and indications for use of the EarlySense (EverOn) System is identical to the EverOn 1.0 (K092062) predicate device, while the monitoring of oxygen saturation is encompassed within the intended use and indications for use of the oximeter predicate device Avant 9600 Pulse Oximeter (K040589). Incorporation of an oximeter module into a physiological data monitor, a well understood technology, is shared by other cleared devices.

Testing was performed in order to demonstrate the safety and performance of the EarlySense System and to demonstrate that as a result of combining the EarlySense technology and a standard OEM, no new safety and effectiveness issues, in comparison to its predicate devices, are raised. In summary, the EarlySense System is as safe and effective as its predicate devices for its intended use and is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness issues.

Performance Testing

A set of software and bench testing was performed in order to demonstrate the performance and accuracy of the EarlySense System and to verify that it does not raise any new safety and effectiveness issues in comparison to its predicate devices. The testing included the following:

- Electrical safety and electromagnetic compatibility testing according to IEC 60601-1 (and amendments), and IEC 60601-1-2 (and amendment) standards.
- Software verification and validation testing was conducted to evaluate the performance of the EarlySense System and to verify that it performs according to its specifications described in the Software Requirements Specifications (SRS).
- Bench testing including demonstrating the accuracy of the oximetry data display and SpO_2 alerting feature.

Summary

The EarlySense System has the same or similar intended uses and indications, technological characteristics, and principles of operation as its predicate devices. Based on the performance testing results, including software verification and validation process and bench testing, the analysis of the similarities and differences, EarlySense Ltd. believes that the EarlySense System is substantially equivalent to its predicates without raising new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Delia Argaman
Vice President Clinical and Regulatory Affairs
EarlySense Limited
12 Tzvi Street
Ramat Gan
Israel 52504

JUN - 8 2012

Re: K120465
Trade/Device Name: EarlySense (EverOn™) System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: BZQ
Dated: May 23, 2012
Received: May 29, 2012

Dear Ms. Argaman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: EarlySense (EverOn™) System

The EarlySense (EverOn) System is intended for continuous measurement of respiration rate, heart rate and movement, in an automatic contact-less manner, at home, hospital or clinic setting. The system is indicated for use in children, adolescents and adults. The operation of the EarlySense has been studied in children (weight ≥ 10 Kg) and adults (weight <111 Kg) during sleep and resting condition. In addition, EarlySense (EverOn) System can continuously monitor oxygen saturation of arterial hemoglobin (SPO2) using pulse oximetry in pediatric (ages 2 years and older), adolescents, and adults at home, hospital, or clinical settings.

Prescription Use __√_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
ivision of Anesthesiology, General Hospital
fection Control, Dental Devices

510(k) Number: K120465